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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,723	12/15/2005	Richard Einstein	BJS-3665-166	5102
23117 7590 08/08/2008 NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203				
EXAMINER				
AEDER, SEANE				
ART UNIT		PAPER NUMBER		
1642				
MAIL DATE		DELIVERY MODE		
08/08/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/560,723

**Applicant(s)**

EINSTEIN ET AL.

**Examiner**

SEAN E. AEDER

**Art Unit**

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 2 and 16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 is/are allowed.
- 6) ☒ Claim(s) 2 and 16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_\_

***Detailed Action***

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/28/08 has been entered.

Claims 1, 2, and 16 are pending.

Claims 1, 2, and 16 have been amended by Applicant.

Claims 1, 2, and 16 are currently under consideration.

***Rejections Withdrawn***

The rejection under 35 U.S.C. 112, first paragraph, is withdrawn.

The rejection of claim 1 under 35 U.S.C. 102(e) is withdrawn.

***Response to Arguments***

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 16 remains rejected and claim 2 is rejected under 35 U.S.C. 102(e) as being anticipated by Gish et al (US 2007/0014801 A1; filed 10/12/01) for the reasons stated in the Office Action of 4/10/07, the reasons stated in the Office Action of 11/28/07 and for the reasons set-forth below.

Amended claim 2 is drawn to "A" nucleic acid of claim 1, which comprises at least a fragment of SEQ ID NO:92 encoding SEQ ID NO:183. It is noted that "a" nucleic acid of a particular nucleic acid sequence differs from "the" nucleic acid of a particular sequence. For instance, "a" nucleic acid of a particular sequence encompasses nucleic acids sharing as few as a single nucleotide with said particular sequence. Because "the" nucleic acid of claim 1 comprises "a", "t", "g", and "c" nucleotides, any nucleic acid comprising "a", "t", "g", or "c" nucleotides is "a nucleic acid of claim 1". Further, it is noted that SEQ ID NO:183 is encoded by "a", "t", "g", and "c" nucleotides. Therefore, claim 2 encompasses any nucleic acid comprising "a", "t", "g", or "c" nucleotides. Claim 16 is drawn to a diagnostic kit for detection of prostate cancer which comprises "a" nucleic acid according to claim 1 or 2 and a detectable label. Again, it is noted that "a" nucleic acid of a particular nucleic acid sequence differs from "the" nucleic acid of a particular sequence. Therefore, claim 16 encompasses any kit comprising a detectable label and a nucleic acid comprising "a", "t", "g", or "c" nucleotides. Further, claim 16 appears to contain a statement reciting purpose or intended use. It is noted that

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statements of intended purposes or uses are not considered limitations because they merely state an intended use of the invention rather than any distinct definition of any of the claimed invention's limitations (see *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999)). Thus, recitation of statements describing the claimed kit as a kit that is intended to be used to detect prostate cancer are not given patentable weight and are not limitations to the claims.

Gish et al teaches a nucleic acid sequence that is expressed by human prostate cancer cells, SEQ ID NO:271 (see paragraph 7, in particular). SEQ ID NO:271 comprises a, "t", "g", and "c" nucleotides. Gish et al further teaches a diagnostic kit comprising SEQ ID NO:271 and a detectable label (see paragraphs 13, 30-32, and 190, in particular).

### ***New Rejections***

#### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 2 and 16 are rejected under 35 U.S.C. 101 because claims 2 and 16, as written, does not sufficiently distinguish over products as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter.

See *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should

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be amended to indicate the hand of the inventor, e.g., by reciting that the nucleic acid is "Isolated" or "Purified". See MPEP 2105.

### ***Claim Rejections - 35 USC § 102***

Claims 2 and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Venter et al (US 6,812,339 B1; 11/2/04).

Venter et al teaches a nucleic acid sequence, SEQ ID NO:30721, which comprises a", "t", "g", and "c" nucleotides and encodes the first 18 amino acids of instant SEQ ID NO:183 (see sequence comparison below, in particular). Venter et al further teaches a kit comprising SEQ ID NO:30721 and a detectable label (see liens 35-42 of column 17, in particular).

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Alignment Scores:
Pred. No.:      5.7e-07      Length:      601
Score:          90.00       Matches:     18
Percent Similarity: 100.0%   Conservative: 0
Best Local Similarity: 100.0% Mismatches:     0
Query Match:    100.0%      Indels:       0
DB:             3          Gaps:         0

US-10-560-723-183 (1-18) x US-09-949-016-30721 (1-601)

QY          1 ValGluThrGluPheHisArgValSerGlnAspGlyLeuAspLeuLeuThrSer 18
            |||||||
Db          283 GTAGAGACGGAGTTTCACCGTGTAGCCAGGATGGTCTCGATCTCCTGACCTCG 230

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### ***Allowable Subject Matter***

Claim 1 is allowed.

### ***Summary***

Claims 2 and 16 are rejected.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SEAN E. AEDER whose telephone number is (571)272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sean E Aeder/  
Examiner, Art Unit 1642

